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(54) Titre : CABLE DE CATHETER MEDICAL EN NICKEL-TITANE, A SURFACE GLISSANTE
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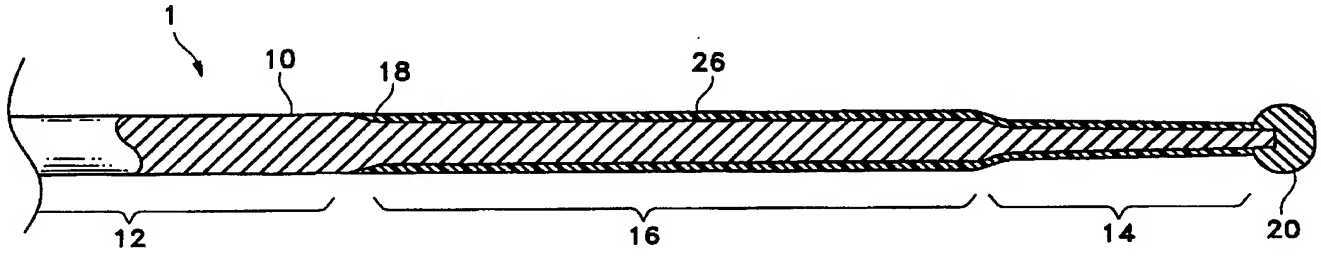

(57) Abrégé/Abstract:
This invention is a medical device for use in catheterization procedures. More specifically, it is a medical catheter wire for use within a catheter lumen and having a super-elastic metallic core coated with lubricious coating and having a distal region desirably with reduced stiffness that ends in an enlarged distal tip. The device may be used as a valve wire in combination with a single lumen balloon catheter or as a wire pusher in combination with an introducer delivery catheter that coaxially houses a helical vaso-occlusive coil.

ABSTRACT

This invention is a medical device for use in catheterization procedures. More specifically, it is a medical catheter wire for use within a catheter lumen and having a super-elastic metallic core coated with lubricious coating and having a distal region desirably with reduced stiffness that ends in an enlarged distal tip. The device may be used as a valve wire in combination with a single lumen balloon catheter or as a wire pusher in combination with an introducer delivery catheter that coaxially houses a helical vaso-occlusive coil.

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NICKEL-TITANIUM, LUBRICIOUS MEDICAL CATHETER WIRE

FIELD OF THE INVENTION

This invention is a medical device for use in catheterization procedures. More specifically, it is a medical catheter wire for use within a catheter lumen and having a super-elastic metallic core coated with lubricious coating and having a distal region desirably with reduced stiffness that ends in an enlarged distal tip. The device may be used as a valve wire in combination with a single lumen balloon catheter or as a wire pusher in combination with an introducer delivery catheter that coaxially houses a helical vaso-occlusive coil.

BACKGROUND OF THE INVENTION

Percutaneous catheterization is a procedure that allows for the administration of medical therapy or the taking of diagnostic measurements at a distally remote internal body site without the need for direct surgical access to that target site. The less invasive catheterization procedures allow for medical devices, such as catheters and guidewires, or their assemblies to be inserted into the body at an initial access site that is remote from the target internal site. Such devices or assemblies may then guided through the channels of the body, such as through the vasculature, via X-ray visualization, until the distal end portion of the catheter or guidewire reaches the target site. Treatment or diagnosis is then achieved at the distal

end portion of the device via manipulation of the proximal end portion extending outside the patient's body.

One type of medical device useful in many catheterization procedures is the "guidewire." Guidewires are elongate medical devices having metallic cores that are designed to provide a pathway over which catheters are guided through the bends, loops, and branches forming the blood vessels within the body. One method of using a guidewire to direct the catheter through the tortuous paths of these lumenal systems involves the use of a torqueable guidewire which is directed as a unit with the catheter from a body access point such as the femoral artery to the tissue region containing the target site. The guidewire typically has a small bend its distal end, and may be guided by alternately rotating and advancing the guidewire along the small vessel pathway to the desired target. The guidewire and the catheter are advanced by alternately moving the guidewire along a distance in the vessel pathway, holding the guidewire in place, and then advancing the catheter coaxially along the axis of the guidewire until it reaches the portion of the guidewire already advanced farther into the human body.

The difficulty in accessing remote body regions, e.g., the body's periphery or the soft tissues within the body such as the brain and the liver, present apparent challenges to guidewire designs. A catheter and its coaxially housed guidewire must be both flexible to allow the combination to follow the complicated path through the tissue, and yet stiff enough to allow the distal end of the catheter to

be manipulated by the physician from the external access site. It is common that the catheter is as long as a meter or more. It is also common that the guidewire is longer than the catheter such that the guidewire extends both proximally and distally of the coaxial catheter to allow for guidewire manipulation and sub-selective tracking in the vasculature.

To meet the performance requirements as just described, guidewires may be constructed having tapers or transitions of materials along the guidewire length to vary the wire flexibilities. Some guidewires have included super-elastic alloy cores, hydrophilic coatings, and enlarged distal tips in order to achieve the requisite guidewire functionalities.

Examples of some catheter guidewires used in guiding a catheter through the human vasculature that have variable flexibility constructions may be found in the following references: U.S. Patent Nos. 3,789,841; 4,545,390; 4,619,274; and. 5,095,915.

Other guidewire disclosures have included use of various super-elastic alloys in an attempt to achieve some of the noted sub-selecting and guiding functions. Examples of specific Ni-Ti alloys are disclosed in U.S. Patent Nos. 3,174,851; 3,351,463; and 3,753,700. Examples of some references disclosing guidewires using super-elastic alloys are found in the following references: U.S. Patent 4,925,445;

WO91/15152 (to Sahatjian et al. and owned by Boston Scientific Corp.); U.S. Patent 4,665,906; U.S. Patent 4,969,890; U.S. Patent 4,984,581; U.S. Patent No. 5,069,226; U.S. Patent No. 5,171,383; and Published European Patent Application 0,515,201-A1.

Other references disclosing the use of hydrophilic polymers, with or without a polymeric tie layer, to increase the surface lubricity of guidewires having superelastic metal alloy core construction include: U.S. Patent No. 5,443,907 to Slaikeu, et. al; U.S. Patent No. 5,129,890 to Bates, et. al.; Published European Patent Application 0,519,604-A2. A further example of a guidewire having a specifically beneficial shape memory alloy for its metallic core, a hydrophilic coating, and optionally a polymeric tie layer between the two is disclosed in EP 714 673 A2 to Palermo et al., published June 5, 1996.

References disclosing guidewires having an enlarged wire tip on a superelastic alloy core that is hydrophilically coated include U.S. Patent No. 5,243,996 to Hall. Hall discloses a wire guide having a mandrel of superelastic metallic material, such as nitinol, and having a reduced-diameter portion in its distal region. A flexible radiopaque platinum coil is attached at the distal region of the mandrel and coaxially surrounds a portion of the distal region. At least one polymer layer may be used to coat the mandrel for increased lubricity. The lubricious covering may be a hydrophilic coating on the coil and a majority of the mandrel, leaving the proximal portion uncoated for ease of physician manipulation.

A further example of a guidewire having a nickel-titanium alloy core and an enlarged tip, although not disclosing use of a hydrophilic polymer, is found in U.S. Patent 4,991,602 to Amplatz et al. Amplatz et. al. suggests a flexible guidewire made up of a shape memory alloy, such as the nickel-titanium alloy known as nitinol.* The guidewire is one having a single diameter throughout its midcourse, is tapered toward each end, and has a bead or ball at each of those ends. The bead or ball is selected to allow ease of movement through the catheter into the vasculature. The guidewire is symmetrical so that a physician cannot make a wrong choice in determining which end of the guidewire to insert into the catheter. The patent suggests that wound wire coils at the guidewire tip are undesirable. The patent further suggests the use of a polymeric coating (PTFE) and an anticoagulant.

A variety of wire devices, other than guidewires, have also been designed for optimally performing functions in medical device assemblies other than providing a rail for guiding over-the-wire catheters to remote internal body spaces. For example, a control wire or deflector wire for use in a guideable catheter assembly is disclosed in U.S. Patent No. 5,419,340 to Stevens. Stevens discloses the control wire as having a stainless steel core wire, a coating that may be a hydromer, and a ball tip that may be approximately .032" and rounded to promote axial travel within a catheter without binding. The control wire is resiliently biased in a linear orientation for the purposes of selectively deflecting a curved distal portion of a catheter into relaxed and unrelaxed positions.

*Trade-mark

Another type of useful medical wire device, not necessarily a guidewire, has been disclosed to provide a valving mechanism when assembled with certain types of "single-lumen" balloon catheters. "Single lumen" balloon catheters generally have one lumen that facilitates balloon inflation and at the same time is co-axial with the guidewire. A valve mechanism is usually provided on the wire (or on the catheter) such that a fluid seal may be selectively achieved between the wire and the catheter. The wire is slidable within the lumen and may be advanced and torqued relatively independently of the catheter in order to select and track to remote sites. Yet, the lumen may be tightly sealed onto the wire via the valve mechanism provided for balloon inflation when desired.

Examples of balloon catheters that generally have one inflation lumen that is also coaxially disposed about a guide wire having a valve member thereon are disclosed in U.S. Patent Nos. 4,813,934 to Engelson, et al.; 5,437,632 to Engelson, et al.; 5,304,198 to Samson; and 5,304,198 to Walker, et al.

A further type of medical wire device is a wire pusher used for advancing a device through the delivery lumen of a delivery catheter and out a distal port thereof and into an internal body space. More specifically, wire pushers have been used to advance a type of artificial vaso-occlusion device, pushable vaso-occlusion coils, through a delivery catheter lumen and out a distal port to occlude

an internal body space. The significance of this type of wire pusher device to the current invention will be discussed in more detail immediately below.

Artificial vaso-occlusion is a procedure wherein an implantable medical device is delivered, usually through the delivery lumen of a delivery catheter, into a remote internal body space to occlude that space. Examples of medical malformations that have been occluded using artificial vaso-occlusion techniques are aneurysms, arterio-venous malformations, and vessels leading to tumorous tissues.

A highly respected implantable device for artificial vaso-occlusion is the vaso-occlusive coil. Various types of vaso-occlusion coil devices and related methods are known, primarily including detachable coils and pushable coils. Pushable coils use devices known as pushers to advance the coil through a delivery catheter and into the body space for occlusion. Pushable vaso-occlusive devices are most relevant to the current invention.

The detachable vaso-occlusion coil is generally detachably integrated with or attached at its proximal end with an elongate pusher and is delivered to a desired location for occlusion, by means of the pusher, through a delivery catheter which terminates at or near the entrance zone of the desired location. Once the coil is extended out of the delivery catheter and into the desired location, the coil is detached from the pusher and left as an implant. The detachment means may be mechanical,

such as the type described in U.S. Patent No. 5,250,071 to Palermo, or may be electrolytic, such as the type described in U.S. Patent No. 5,122,136 to Guglielmi et al.

"Pushable" vaso-occlusion devices or coils are not integrated with a pusher but are independent devices. Such devices are generally pre-packaged in pre-loaded introducer catheters as cartridges and discharged therefrom into a distal delivery catheter. In one type of pushable vaso-occlusion coil, pressurized fluid may hydraulically deliver the pre-loaded implant, such as is disclosed in the following references: U.S. Patent No. 5,133,731 to Butler et al; U.S. Patent No. 5,167,624 to Butler et al., EP 734 697 A2 for "Liquid Coils with Secondary Shape", published October 2, 1996.

One pushable vaso-occlusion coil assembly using a non-integrated pusher is disclosed in U.S. Patent No. 5,382,260 for "Embolization Device and Apparatus Including an Introducer Cartridge and Method for Delivering the Same," to Dormandy, et al. Dormandy '260 discloses an introducer cartridge having a distal extremity with a tapered tip and a hub mounted on a proximal extremity. The cartridge is introduced into a coil delivery catheter in a catheter system as described earlier, and a stylet is used to push the embolization device out of the introducer cartridge into a passage in the coil delivery catheter. A wire that Dormandy characterizes as a guide wire is then used to push the coil through the coil delivery catheter until it advances beyond the catheter tip and into the desired site for

occlusion. Such a wire, however, does not "guide" other devices coaxially over its shaft or otherwise function as a "guidewire" either in the classical sense or as that term has been herein defined in this specification.

Another pushable vaso-occlusion coil that is pre-loaded in an introducer cartridge and is delivered via a pusher device is disclosed in U.S. Patent No. 5,382,259 to Phelps et al. Phelps discloses a vaso-occlusion coil that may be continuous or segmented, onto which a fibrous, woven or braided, tubular covering or element is attached. Phelps further discloses that the coil devices may be supplied prepackaged in a sterile cannula which is adapted to engage the proximal end of a delivery catheter. To deliver the Phelps et al. coil device, the distal end of a delivery catheter is placed adjacent to a desired occlusion site, and the coil-containing cannula is placed into engagement with the proximal end of the catheter. The coils are then transferred from the cannula lumen into the catheter lumen by exerting a force on the proximal end of the coil. The reference discloses use of a flexible type of pusher device to push the coil through the delivery catheter and out its distal end to the desired site.

Another vaso-occlusion coil that is pre-loaded in an introducer cartridge and is delivered via a separate pusher is disclosed in U.S. Patent No. 4,994,069 to Ritchart et al. Ritchart et al. discloses a coiled wire for use in small-vessel vaso-occlusion and having a convoluted space filling conformation when in a relaxed condition, a linear configuration when in a stretched condition, and a memory from the

stretched to the relaxed condition when released from a delivery catheter into a vessel. Ritchart et al. provides the vaso-occlusion wire in a prepackaged form in a sterile cannula which is adapted to engage the proximal end of the delivery catheter. The cannula is attached to the delivery catheter and the wire is transferred into the delivery catheter by a short wire. A pusher is disclosed for advancing the wire through the delivery catheter.

Another example of an embolic coil that is pre-loaded in an introduction device as a cartridge is described in Dormandy '260. The patent discloses a co-axial telescoping arrangement including a femoral artery sheath, a guiding catheter, and a coil delivery catheter. A C-shaped embolization device such as a coil is provided in an introducer cartridge made of clear transparent plastic such as a radiation sterilizable polycarbonate. A tubular member of the cartridge is bendable but relatively rigid so that it can be utilized as an introducer. A distal extremity of the cartridge is provided with a tapered tip and a hub is mounted on the proximal extremity, the hub also being formed of clear radiation sterilizable polycarbonate.

A pre-loaded tube for delivery of a vein-branch blocking member is also disclosed in U.S. Patent No. 5,342,394 to Matsuno et al. Matsuno discloses an apparatus and method for blocking a vein branch comprising a vein-branch blocking member pushed out of a delivery tube with a push-out member and into the vein. The outer tube is bent and slidably receives an inner tube with a distal storing portion

filled with a vein-branch blocking member. A push-out member pushes out the blocking member in the vein branch. The pre-loaded inner tube is flexible and has a proximal end that is fixed with a grip that is adapted to engage the proximal end of the outer tube in various embodiments. The distal shape of the outer tube is between 60 and 120 degrees and allows the inner tube to be easily inserted in the vein branch branching from the lateral wall of the vein. An embodiment discloses an articulation means for the distal bend, but no way to have a straight end if desired. The proximal end of the tube, however, is straight but is not adapted to be used distally nor is the distal shaped end adapted to straighten and be interchangeably used proximally.

None of the cited references disclose a medical catheter wire having a superelastic metallic core that is at least partially coated with a hydrophilic coating and that has a distal wire section that is substantially straight, unshapeable, and desirably having a distal reduction in wire stiffness and a larger wire tip profile than the distal wire section.

Nor do these references disclose such a medical catheter wire assembled as a valve wire in combination with a single-lumen type of balloon catheter, wherein the enlarged wire tip forms a fluid seal with a valve seat of the balloon catheter.

Nor do these references disclose such a medical catheter wire assembled as a wire pusher in combination with an introducer delivery catheter that co-axially

houses a target delivery device, such as a vaso-occlusive coil, the enlarged wire tip being adapted to cooperate with a proximal device end during advancement of the target delivery device through the introducer delivery catheter.

SUMMARY OF THE INVENTION

The current invention is a medical catheter wire for use within the internal catheter lumens during catheterization procedures. The inventive medical catheter wire includes a superelastic metallic core having a proximal wire section, desirably having an intermediate wire section at least partially coated with a lubricious coating, and a distal wire section at least partially coated with a lubricious coating and optionally being substantially straight and unshapeable and more flexible than the intermediate wire section. The inventive medical catheter wire also has a distally placed enlarged wire tip adjacent to the distal wire section, which tip has a larger profile than the distal wire section and is also substantially unshapable. In one further embodiment of the medical wire, there is also a polymeric tie layer between the superelastic metallic core and the hydrophilic coating. In another embodiment, the enlarged wire tip is substantially spherical. In still a further embodiment, the lubricious coating is a hydrophilic coating.

The present invention includes a balloon catheter/valve wire assembly including the medical catheter wire described assembled as a valve wire with a single-lumen type of balloon catheter. The balloon catheter of the assembly typically

has a single lumen housing the valve wire which is fluidly couple to a proximal coupler and to an expandable balloon. A valve seat of reduced inner diameter (compared to the internal diameter of the catheter) is provided within the internal lumen at the balloon tip, the valve seat inner diameter and enlarged wire tip profile being of dimension and material to form a tightly toleranced, coaxial interference fit such that distal fluid flow is blocked when the single lumen of the balloon catheter is pressurized for inflation. In a further embodiment of the balloon catheter of this assembly, the valve seat is compliant such that a fluid seal may be formed with the enlarged wire tip in a mechanically compressive press-fit.

The present invention further includes a medical device delivery system made up of a medical catheter wire assembled as a wire pusher in combination with a delivery catheter and a target device for distal delivery into an internal body space. The delivery catheter of this system includes a proximal delivery coupler, a distal delivery port, and a polymeric delivery shaft defining a delivery lumen extending between the proximal delivery coupler and the distal delivery port. The delivery lumen has an inner diameter adapted to slideably receive the enlarged wire tip and intermediate and distal wire sections. The target device of the system is slideable within the delivery lumen and has a proximal device end portion adapted to cooperate with the wire tip in sliding the target device through the delivery lumen and out the distal delivery port. In a further embodiment of the target device in the system, the

target device is a vaso-occlusive implant, and is further defined in the embodiments as a vaso-occlusive coil.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a cut-away side view of the medical catheter wire of the current invention.

FIG. 2 is a partial side view of a further medical catheter wire embodiment wherein a polymeric tie layer is shown between the superelastic metal alloy core and a lubricious hydrophilic coating.

FIG. 3 shows a cut-away side view of a balloon catheter/valve wire assembly embodiment of the current invention, wherein the medical catheter wire of FIG. 1 is shown assembled as a valve wire in combination with one type of single-lumen balloon catheter.

FIG. 4 shows a perspective view of a medical device delivery system embodiment of the current invention, wherein the medical catheter wire of FIG. 1 and a vaso-occlusive coil are shown in phantom within the delivery lumen of a delivery catheter.

DESCRIPTION OF THE INVENTION

Medical Catheter Wire

FIG. 1 shows a cut-away side view of a medical catheter wire embodiment of the current invention, wherein medical catheter wire (1) is shown to have a proximal wire section (12), an intermediate wire section (16), a distal wire section (14), and an enlarged wire tip (20). Medical catheter wire (1) is also made up of a superelastic metallic core (10) formed of the alloys described below and has a total length typically between about 50 and 300 centimeters. The features of medical catheter wire (1), as shown in FIG. 1 and described in detail below, allow use either as a valve wire in a balloon catheter/valve wire assembly (as shown in FIG. 3) or as a wire pusher in a medical device delivery system (as shown in FIG. 4).

The proximal wire section (12) preferably has a uniform diameter (along its length) of about 0.010 to 0.035 inches, preferably 0.010 to 0.016 inches. The distal wire section may be relatively more flexible than the proximal section. If so, the distal wire section (14) extends for 3 to 30 centimeters or more of the distal end of the medical catheter wire (1). Any reduction in flexibility may be achieved in a variety of ways, e.g., through changes in material along the wire length (such as in the particular superelastic alloy composition of the metallic core in the section) or through changes in geometry (such as through a ground reduction in the superelastic core outer diameter in the section). In any case, the distal wire section (14), although flexible, is

substantially straight and unshapeable, particularly desirable aspects of the wire as a valve wire and a wire pusher in the preferred embodiments of FIGS. 3 and 4.

Also shown in FIG. 1 is intermediate wire section (16). The intermediate wire section may comprise a portion of the metallic core having a slightly reduced outer diameter. Desirably, it has a coating on its outer surface of such thickness so to form a continuous outer diameter with proximal wire section (12). However, the intermediate wire section (16) may be continuously tapered, may have a number of tapered sections or sections of differing diameters, or may be of a uniform diameter along its length. If intermediate wire section (16) is of a generally uniform diameter, the medical catheter wire core may neck down as is seen at (18).

Distal wire section (14) of the medical catheter wire (1) is also shown ending distally in an unshapeable, enlarged wire tip (20), which is shown to have a larger profile than distal wire section (14). The unshapeability of enlarged wire tip (20), similar to that of the distal wire section (14), allows for the medical catheter wire to be optimally durable under the compressive push forces of use as a valve wire or as a wire pusher. The enlarged wire tip profile also optimizes use of the device as a valve wire or wire pusher, since the geometry of the distal wire end must be adapted to engage a cooperating valve seat or proximal device end, as is respectively required in the embodiment of FIG. 3. The particular benefits of these features will be explained in more detail below. The enlarged wire tip (20) may also be radiopaque

and made from materials including but not limited to platinum, tungsten, gold, or alloys thereof. Such radiopaque metals allow knowledge of the position of enlarged wire tip (20) during the process of inserting the medical catheter wire through a coaxial catheter disposed in the vasculature.

The enlarged wire tip (20) may be formed on medical catheter wire (1) using a variety of methods that result in an unshapeable tip. One acceptable method involves soldering a radiopaque metal element onto the very tip of the metal core and then melting the metal element, such as with a laser or using electrical discharge techniques as may be apparent to one of ordinary skill. Such radiopaque metal element may be a metal coil placed coaxially over the end of the core and then attached as just described. Or, the metal element may be a metallic band coaxially placed and secured in a similar manner. The result of these methods produces an enlarged wire tip (20) that is preferably substantially solid, which optimizes radiopacity and unshapeability of the tip.

All or part of the proximal wire section (12), intermediate wire section (16), and distal wire section (14) may be coated with a thin layer of polymeric material (26) to improve its lubricity without adversely affecting the flexibility of the medical catheter wire. As is discussed below, when using hydrophilic polymers as the coating material, it is often desirable to use a polymeric tie layer on the medical catheter wire core.

The medical catheter wire of the present invention, such as the medical catheter wire (1) embodiment of FIG. 1 mentioned above, may be used as a valve wire in a single-lumen type of balloon catheter, or as a wire pusher in a delivery catheter which is made up of an elongate polymeric tubular member having ports at proximal and distal ends. Such catheters are (again) about 50 to 300 centimeters in length, typically between about 100 and 200 centimeters in length. Generally, the polymeric tubular shafts of such catheters have a relatively stiff proximal section which extends along a major portion of the catheter length and one or more relatively flexible distal sections which provide greater ability of the catheter to track a guidewire through sharp bends and turns encountered as the catheter is advanced through the tortuous paths found in the vasculature. Suitable catheters in the preferred catheter/wire assembly embodiments of the present invention are discussed in more detail in FIGS. 3 and 4.

The unshapeable design provided for distal end section (14) and enlarged wire tip (20) allows for the medical catheter wire (1) to be an optimal "push wire" for use internally with such catheters. The term "unshapeability" as defined herein as the ability of such a medical catheter wire to confront another device's surface within the body and push against it, as a part of a particular method, without plastic deformation to the wire. This is a preferred quality either in pushing against a proximal side of a single-lumen valve seat to form a fluid seal for balloon inflation (as is shown and described for assembly 3 of FIG. 3) or in pushing against a target device

for delivery within a lumen of a delivery catheter (as is shown and described for assembly 4 of FIG. 4). Similarly for such "push wire" functionality, it is preferred that the distal wire section (14) and enlarged wire tip (20) be substantially straight, allowing for such push forces as just described to be most efficiently transmitted to the confronting end of enlarged wire tip (20) with minimized prolapse. The medical catheter wire (1) thus has no steering or subselecting function that are required of guidewires; otherwise the wire would be shaped or shapeable and may not provide the beneficial pushing qualities just described.

Guidewires made of certain alloys, particularly Ni-Ti alloys, have super-elastic properties and retain those properties during traversal through the catheter when disposed in the vasculature. Yet such guidewires are sufficiently pliable that they provide the physician using the medical catheter wire with enhanced "feel" or feedback. The preferred alloys do not incur significant unrecovered strain during use, such as when bent within catheters in tortuous anatomy or when under compressive forces of pushing against a valve seat or against a target delivery device within a delivery catheter lumen.

The material used in the medical catheter wires of this invention are of shape memory alloys which exhibit super-elastic/pseudo-elastic shape recovery characteristics. Various acceptable alloys showing these characteristics are known. For instance, alloys disclosed in U.S. Patent Nos. 3,174,851; 3,351,463; and

3,753,700 would be acceptable. The alloy disclosed in the '700 patent may be particularly desirable among those disclosures because of the increased pushability concomitant with the higher modulus of the material disclosed therein as having an increased iron content. These metal alloys are characterized by their ability to be transformed from an austenitic crystal structure to a stress-induced martensitic (SIM) structure at certain temperatures, and return elastically to the austenitic structure when the stress is removed. These alternating crystalline structures provide the alloy with its super-elastic properties. One such well-known alloy, nitinol, is a nickel-titanium alloy. It is readily commercially available and undergoes the austenite-SIM-austenite transformation at a variety of temperature ranges between -200C and 300C.

These alloys are especially suitable because of their capacity to elastically recover almost completely to the initial configuration once the stress is removed. Typically there is little plastic deformation, even at relatively high strains. This allows the medical catheter wire to undertake substantial bends as it passes through the delivery catheter in the body's vasculature, and yet return to its original shape once a bend has been traversed without retaining any hint of a kink or a bend. Nevertheless, compared to similar stainless steel medical catheter wires, less force need be exerted against the interior wall of the delivery lumen to deform the medical catheter wire of the invention along the desired path through the delivery catheter, thereby reducing friction against the coaxial catheter.

To achieve the desired result of high strength and enhanced durability even while allowing feedback to the attending physician during use, the physical parameters of the preferred alloys and metal working methods disclosed in U.S. Patent No. 5,409,015 to Palermo, et. al. are highly desirable in the present invention.

As mentioned above, all or part of the medical catheter wire core may be covered or coated with one or more layers of a polymeric material. The coating is applied typically to enhance the lubricity of the medical catheter wire core during its traversal of the delivery catheter lumen. At least a portion of the medical catheter wire core may simply be coated by dipping or spraying or by similar process with such materials as polysulfones, polyfluorocarbons (such as TEFLON*, polyolefins such as polyethylene, polypropylene, polyesters (including polyamides such as the NYLON's*, and polyurethanes; their blends and copolymers such as polyether block amides (e.g., PEBAX*.

It is often desirable to utilize a coating such as those just mentioned on the proximal portion of the medical catheter wire and a coating such as discussed immediately below on the more intermediate and distal wire sections. Any mixture of coatings placed variously on the medical catheter wire is acceptable as chosen for the task at hand.

*Trade-mark

One preferred coating for the core wire of the current invention, particularly preferred for intermediate wire section (16) and distal wire section (14) is shown in cross section in FIG. 2. FIG. 2 shows a typical guide wire core section (2) having a superelastic metallic core (202), a polymeric tie layer (204), and a lubricious coating (206), which is most preferably a hydrophilic coating. The material composition and coating methods for forming this coated wire assembly may also be similar to the various embodiments disclosed in EP 714 673 A2 to Palermo, et al. Preferred compositions include polymeric materials containing polyvinylpyrrolidone or polyethyleneoxide.

Balloon Catheter/Valve Wire Assembly

FIG. 3 shows the medical catheter wire (1) of FIG. 1 assembled as a valve wire in combination with one type of "single-lumen" balloon catheter (320), forming balloon/wire assembly (3).

In this embodiment, the single-lumen balloon catheter design shown may be similar to that disclosed in U.S. Patent No. 5,304,198 to Samson. Inflation shaft (327) of balloon catheter (320) is shown to provide an wire lumen (329) adapted to slideably receive medical catheter wire (1) and also that fluidly couples a proximal inflation coupler (not shown) with expandable balloon (323) (which is shown to be in

an expanded state). A portion of medical catheter wire (1) is shown to be coaxially housed within wire lumen (329), and is shown extending coaxially under balloon (323), and distally through balloon catheter tip region (331).

In the balloon catheter tip region (331) is a valve seat (333), which is shown in FIG. 3 to be formed underneath a radiopaque tip marker (335). This valve seat (333) is designed to have a tight tolerance with the profile of enlarged wire tip (20), forming an interference fit therewith. This interference fit forms a barrier to distal fluid flow from the interior space of balloon (323), such that the balloon may be controllably inflated at elevated pressures. Preferably, such valve seat is formed of a compliant polymer and of lower inner diameter that the wire tip profile such that the enlarged wire tip (20) may be pushed coaxially into the valve seat in a press-fit to form a mechanically compressive seal to fluid flow.

In addition, the proximal inflation coupler (not shown) of balloon catheter (320) preferably comprises an adjustable seal around medical catheter wire (1) at intermediate wire section (16) or the proximal wire section (not shown) to provide a barrier to proximal fluid flow during balloon inflation. For instance, a conventional type of rotating hemostatic valve mechanism may be provided at the proximal inflation coupler.

The medical catheter wire (1) in FIG. 3 is shown to have enlarged wire tip (20) abutting a proximal edge of valve seat (333). This arrangement would be achieved, for instance, where balloon catheter (320) is advanced distally into an internal body site over a conventional guidewire, with the guidewire subsequently removed and replaced by the novel valve wire for balloon inflation. The design of medical catheter wire (1) purely as a valve wire in this assembly may be optimized for forming the seal with valve seat (333), without the need for steerability, and atraumatic trackability design requirements found in standard guidewires. For example, the more narrow functionality may allow for a much stiffer distal wire section (14) proximally of enlarged wire tip (20) than a guidewire would allow. Such increased stiffness may allow for more push force at the enlarged wire tip (20) such that a tighter interference fit may be achieved at the valve seat (333). This tighter fit, in turn, may allow for higher inflation pressures to be achieved before the valve seal is compromised. Additionally, the super-elastic alloy core, together with the preferred hydrophilic coating, are designed to optimize the ability to advance the wire through the single-lumen and push against the valve seat (333) without permanently deforming the wire.

FIG. 3 also shows distal wire section (14) having a reduced outer diameter relative to the intermediate wire section (16), the transition to the reduced outer diameter being shown beneath expandable balloon (323). However, it may be preferable to lengthen the reduced outer diameter distal wire section (16) so that it

traverses the balloon and extends even proximally within the inflation shaft (327) region when the enlarged wire tip (20) forms the seal with valve seat (333). In such a configuration, a larger intralumenal clearance is created within the inflation lumen (which is also the wire lumen) which may increase inflation/deflation times of the balloon. Additionally, such lengthened region of profile reduction may allow for a tapered outer diameter for the distal portions of inflation shaft (327) and the other more distal balloon catheter components shown.

Medical Device Delivery Assembly

FIG. 4 is a perspective view of medical catheter wire (1) of FIG. 1 in a medical device delivery assembly of the current invention. In this embodiment, the novel medical catheter wire of the current invention is assembled as a wire pusher to delivery a medical device through the delivery lumen of a delivery catheter. More specifically to the particular embodiment of FIG. 4, medical catheter wire (1) is shown in phantom to be slideably within the coaxial delivery lumen of delivery catheter (400), wherein enlarged wire tip (20) is shown to proximally abut a proximal coil end (455) of a vaso-occlusive coil (450), which is in this case the target device for delivery.

Delivery catheter (400) of assembly (4) may be an "over-the-wire" type of delivery catheter that generally is guided to a desired internal body site by riding on its delivery lumen coaxially over a guidewire. One type of a highly beneficial "over-the-wire" delivery catheter that would be suitable in the embodiment of assembly (4) of the

current invention is guidewire is described in U.S. Patent No. 4,739,768 to Engelson. A further type of delivery catheter that may be a suitable component to assembly (4) a flow-directable type of delivery catheter, such as that described in U.S. Patent No. 5,336,205 to Zenzen. These delivery catheters generally have a stepwise reduction in stiffness, such that there is a flexible distal region (440) for tracking in tortuous anatomy, and a relatively more stiff proximal region (420) for physician manipulation and transmission of proximal push forces to distal catheter regions. One or more intermediate sections may also be provided, such as is shown at (430) in FIG. 4. Additionally, a proximal delivery coupler (410) and a distal tip marker (445) are preferred components of delivery catheter 400, as may be apparent to one of ordinary skill.

Vaso-occlusive coil (450) preferably is a non-detachable, pushable type of vaso-occlusion coil, such as that disclosed in U.S. Patent Nos.5,382,259; 5,382,260; 4,994,069; and 5,342,394. Another desirable type of non-detachable vaso-occlusion coil that may be useful in the present invention is also shown in FR 423648 A which published March 22, 1996.

In general, such pushable vaso-occlusion coils are helically wound wires that have a primary helical geometry that forms a primary helix lumen with a primary helix inner diameter and a primary helix outer diameter. The ends of such helical

coils are usually filled or otherwise terminated with a soldered, welded, or otherwise rounded metallic ball or cap. The vaso-occlusion coil is often provided with a secondary geometry, which may also be a secondary helix, having a secondary inner diameter and a secondary outer diameter.

Examples of known commercial vaso-occlusive coil embodiments that may be used in this invention have primary helix outer diameters between about 0.008" and 0.035", wherein the delivery catheters adapted for delivering such coils into the body are closely toleranced above those dimensions. Enlarged wire tip (20) should be adapted of dimension and shape to confront the rounded end of vaso-occlusion coil (450). Preferably, enlarged wire tip (20) has a rounded end to aid in smooth slideable delivery within the delivery lumen of the delivery catheter. Also preferred, the wire tip profile of enlarged wire tip (20) is equal to or less than the primary helix outer diameters, such as being in the range of .006" - .010" for use with a .010" primary helix outer diameter, or being in the range of .014"-.018" for use with a .018" primary helix outer diameter.

In preferred mode of operation for the assembly (4) of FIG. 4, vaso-occlusion coil (450) is provided pre-loaded in a sterile kit within an introducer cannula. The delivery catheter of the assembly is percutaneously introduced into the body and advanced translumenally into a remote internal body space. A distal end of the cannula is coaxially introduced into the proximal hub of the delivery catheter and a

separate plunger may be used to eject the pre-loaded coil from the cannula and into the delivery catheter lumen. Or, alternatively, the novel wire pusher of the present invention may be used for this purpose.

Once the coil is introduced into the delivery catheter lumen, the wire pusher is advanced until the enlarged wire tip confronts the proximal device end of the coil. Continued advancement of the wire pusher advances the coil along the delivery lumen until it is expelled from a distal port of the delivery catheter and into the desired internal body space for artificial occlusion.

The above is a detailed description of particular embodiments for the invention. Any combination of the disclosed embodiments is contemplated as within the scope of the present invention. It is also recognized that departures from the disclosed embodiments may be made and obvious modifications will occur to a person skilled in the art without departing from scope of the invention.

I CLAIM AS MY INVENTION:

1. A medical catheter wire assembly for use within a medical catheter lumen, comprising:

a superelastic metallic core having a proximal wire section, an intermediate wire section, a substantially straight and unshapeable distal wire section being more flexible than said intermediate wire section, and a lubricious coating at least partially covering said intermediate and distal wire sections so as to form an outer diameter on said intermediate wire section which is substantially equal to and continuous with an outer diameter of said metallic core in said proximal wire section; and

an enlarged wire tip adjacent to said distal wire section and having a larger wire tip profile than said distal wire section and being substantially unshapeable.

2. The medical catheter wire assembly of claim 1, wherein said superelastic metallic core is an alloy of nickel and titanium.

3. The medical catheter wire assembly of claim 2, wherein said alloy of nickel and titanium is nitinol.

4. The medical catheter wire assembly of claim 1, wherein said distal wire section has a smaller outer diameter than said intermediate wire section.

5. The medical catheter wire assembly of claim 1, wherein said lubricious coating is a hydrophilic coating.

6. The medical catheter wire assembly of claim 5, further comprising a polymeric tie layer between said superelastic metallic core and said hydrophilic coating.

7. The medical catheter wire assembly of claim 1, wherein said enlarged wire tip is comprised of a radiopaque material.

8. The medical catheter wire assembly of claim 7, wherein said radiopaque material is a metal.

9. The medical catheter wire assembly of claim 8, wherein said metal is chosen from the group consisting of platinum, tungsten, and gold.

10. The medical catheter wire assembly of claim 1, wherein said wire tip is substantially spherical.

11. The medical catheter wire assembly of claim 1, further comprising:

a balloon catheter having a proximal coupler, an expandable balloon, a balloon tip distal of said balloon and with a distal wire port, a wire lumen extending between

said proximal coupler and said distal. wire port and fluidly coupling said expandable balloon with said proximal coupler, and a valve seat located interiorly of said wire lumen and having a reduced inner diameter from said wire lumen, said reduced inner diameter of said valve seat being adapted to removably engage said enlarged Wire tip in an interference fit to form a fluid seal such that fluid interior of said wire lumen may be pressurized to cause balloon expansion.

12. The medical catheter wire assembly of claim 11, wherein said valve seat is comprised of a compliant polymeric material and has a valve seat inner diameter less than said wire tip profile, said enlarged wire tip being adapted to coaxially enter said valve seat in a press fit to mechanically form said fluid seal.

13. The medical catheter wire assembly of claim 1, further comprising:

a delivery catheter having a proximal delivery coupler, a distal delivery port, and a polymeric delivery shaft defining a delivery lumen extending between said proximal delivery coupler and said distal delivery port, said delivery lumen having an inner diameter adapted to slideable receive said enlarged wire tip and inter-mediate and distal wire sections; and

a target device being slideable within said delivery lumen and having a proximal device end portion adapted to cooperate with said enlarged wire tip in sliding said target device through the delivery lumen and out the distal delivery port.

14. The medical catheter wire assembly of claim 13, wherein said target device is a vaso-occlusive implant adapted for artificially occluding a body space.

15. The medical catheter wire assembly of claim 14, wherein said vaso-occlusive implant is a vaso-occlusive coil comprised of a helically wound wire, being slideable within said delivery lumen, and having a helix inner diameter smaller than said wire tip profile.

16. The medical catheter wire assembly of claim 15, wherein said vaso-occlusive coil has an expanded coil diameter when in a radially relaxed state that is greater than said delivery lumen inner diameter, said vaso-occlusive coil being radially compressible from said radially relaxed state to have a compressed coil diameter and being so compressed when disposed within said delivery lumen such that a force is exerted against the delivery lumen wall defining said delivery lumen.

17. The medical catheter wire assembly of claim 13, wherein said superelastic metallic core of said medical catheter wire is comprised of nitinol.

18. The medical catheter wire assembly of claim 13, wherein said wire tip is comprised of solid radiopaque metal.

19. The medical catheter wire assembly of claim 13, wherein said wire tip is substantially spherical.

20. A medical catheter wire assembly for use within a medical catheter lumen, comprising:

a superelastic metallic core having a proximal wire portion, an intermediate wire portion, a substantially straight and unshapeable distal. wire portion being more flexible than said intermediate wire portion, and a hydrophilic coating at least partially covering said intermediate and distal wire portions to form a distal wire section and intermediate wire section, so as to form an outer diameter on said intermediate wire section which is substantially equal to and continuous with an outer diameter of said metallic core in said proximal wire portion; and

an enlarged wire tip adjacent to said distal wire section and having a larger wire tip profile than said distal wire section and being substantially unshapeable.

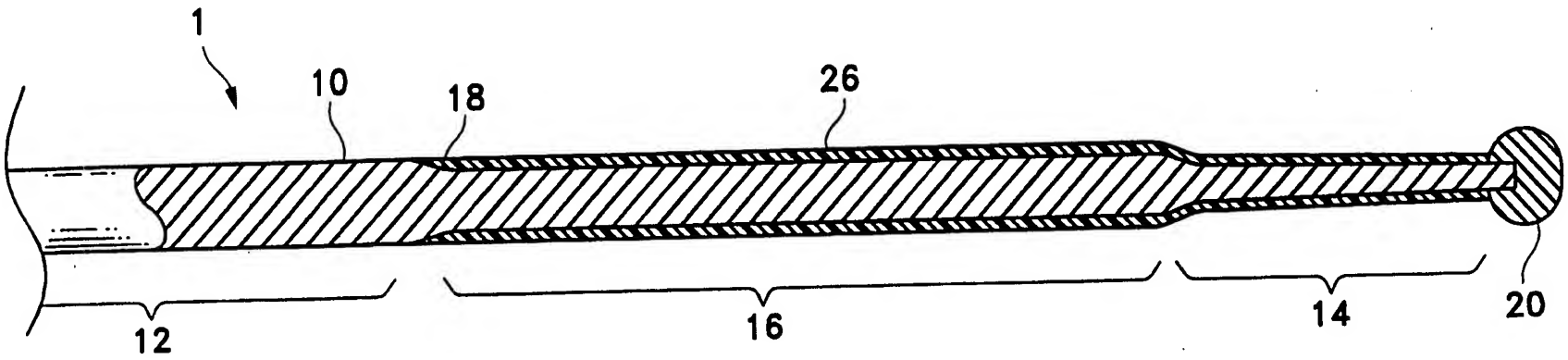

FIG. 1

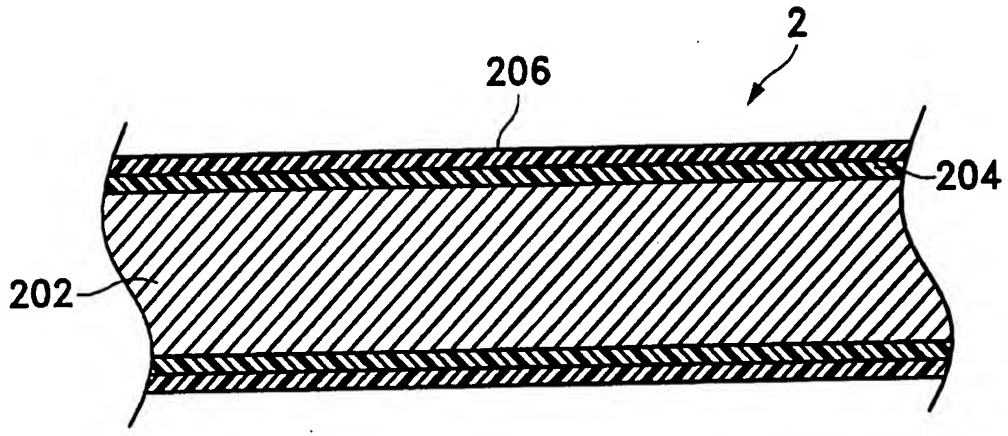

FIG. 2

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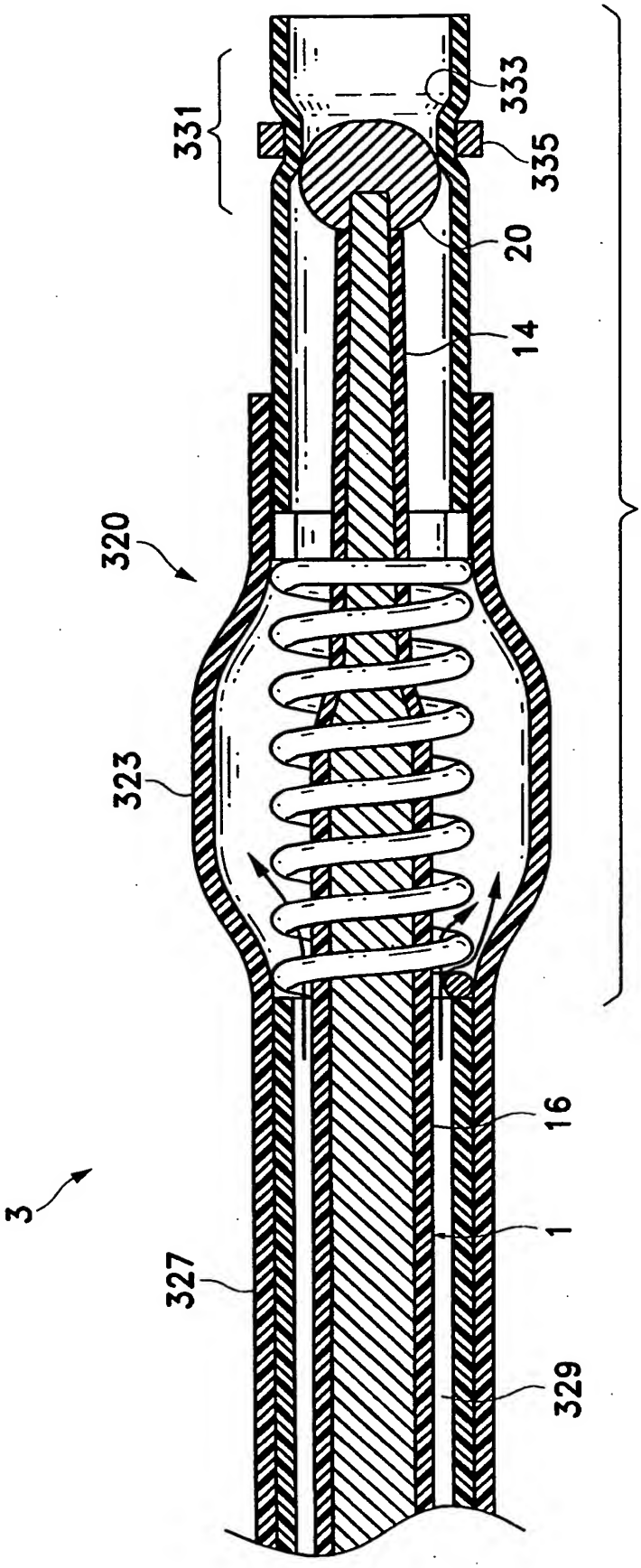

FIG. 3

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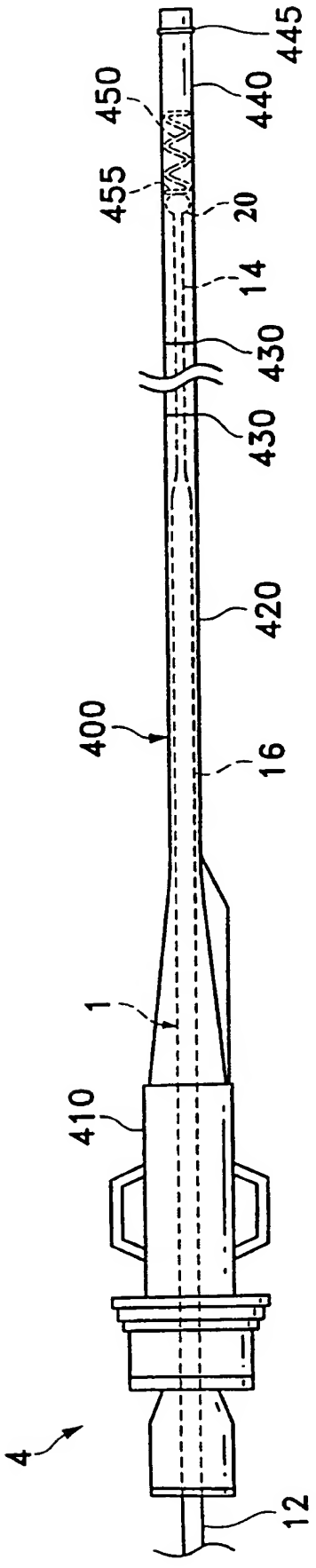

FIG. 4

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